

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN M. LIPARI,  
DAWN M. RAYMOND, and TOM REILAND

Appeal No. 2005-0413  
Application No. 09/216,242

MAILED

MAY 31 2005

U.S. PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

ON BRIEF<sup>1</sup>

Before ELLIS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3-5, 12, and 14-16, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A composition consisting of a fibrate dissolved in at least one structured lipid.
3. A composition of claim 1 wherein the fibrate is fenofibrate.

<sup>1</sup> Appellants waived their request for oral hearing. Paper received April 11, 2005. Accordingly, we considered this appeal on Brief.

4. A composition of claim 1 wherein at least one or more of the structured lipids is selected from the group consisting of caprylic/capric/lauric triglycerides and caprylic/capric/linoleic triglycerides.

The examiner relies on the following references:

Bistrian et al. (Bistrian)	4,871,768	Oct. 3, 1989
Babayan et al. (Babayan)	4,952,606	Aug. 28, 1990
Kikuchi et al. (Kikuchi)	5,506,230	Apr. 9, 1996
Lacy et al. (Lacy)	5,645,856	Jul. 8, 1997
Chavkin et al. (Chavkin)	5,753,255	May 19, 1998

Hyltander, et al. (Hyltander), "Metabolic Effects of Structured Triglycerides in Humans," NCP, Vol. 10, No. 3, pp. 91-97 (1995).

#### GROUND OF REJECTION

Claims 1, 3-5, 12, and 14-16 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lacy, further in view of Babayan, Bistrian and Hyltander.<sup>2</sup>

We reverse.

#### DISCUSSION

Appellants' claims are drawn to a composition (claims 1, 3-5, 12 and 14) and methods (claims 15 and 16) of using the composition. All of appellants' claims depend from, or require the use of the composition recited in from claim

1. As set forth above, claim 1 is drawn to a composition consisting of (1) a fibrate, which can be fenofibrate (see e.g., appellants' claim), and (2) at least one structured lipid, which can be, inter alia, caprylic/capric/lauric triglycerides

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<sup>2</sup> As we understand the examiner's statement of the rejection, Babayan, Bistrian and Hyltander are combined with Lacy either individually or in combination.

and caprylic/capric/linoleic triglycerides (see e.g., appellants' claim 4 and appellants' specification, last paragraph, page 3).

According to the examiner (Answer, page 3), Lacy discloses compositions containing fenofibrate, "a triglyceride (structured lipid), polyglycerol esters of fatty acids (surfactant) and a cosolvent...." The examiner finds (id.), Lacy discloses that the "composition contains [c]apric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7). The examiner recognizes, however, "Lacy does not teach omission of the surfactant." Id. Nevertheless, the examiner concludes (Answer, bridging sentence, pages 3-4), "it is deemed obvious to one of ordinary skill in the art [at the time the invention was made] not to include a surfactant if it is deemed to be not necessary." The examiner, however, offers no evidence to suggest that the components of Lacy's composition that are not present in appellants' claimed composition would be unnecessary in Lacy's composition. In this regard, appellants assert (Brief, page 9), "[t]he claims explicitly exclude the presence of ... other components."

According to Lacy (column 3, lines 39-45), the invention "in its broadest aspect provides a carrier system for a hydrophobic drug which comprises: (a) a digestible oil, and (b) a pharmaceutically acceptable surfactant for dispersing the oil *in vivo* upon administration of the carrier system, said surfactant comprising a hydrophilic surfactant component...." As we understand Lacy's disclosure, Lacy overcomes the disadvantages of using drug in oil alone by including a hydrophilic surfactant to the drug in oil composition.

However, as Lacy points out (column 3, lines 50-52), the majority of hydrophilic surfactants "will inhibit the lipolysis of the digestible oil component." Therefore, to overcome the inhibitory effect of the hydrophilic surfactant, Lacy's composition must also include a lipophilic co-surfactant. Lacy, column 3, lines 52-55. Accordingly, as we understand Lacy's disclosure, Lacy's composition includes four components, (1) a hydrophobic drug, (2) a digestible oil<sup>3</sup>, (3) a hydrophilic surfactant, and (4) a lipophilic surfactant. See e.g., Lacy, column 3, lines 56-67. In contrast, appellants' claimed invention includes only (1) a hydrophobic drug (a fibrate), and (2) at least one structured lipid. Therefore, as we understand the issue on appeal, the question is whether Lacy suggests removing two of the four components of the disclosed composition and if so, would the two remaining components be (1) a fibrate and (2) a at least one medium chain glycerol ester of a fatty acid?

In this regard, we note that Lacy carves out an exception to the use of digestible oils. Specifically, Lacy discloses (column 4, lines 1-5), "[i]f the lipophilic surfactant is itself a digestible oil, or can serve as the source of lipolytic products, then in a modification of the preferred carrier system a separate digestible oil component may be omitted...." According to Lacy (column 6, lines 14-16), surfactants within classes 1-5 above [(see Lacy, column 4, line 39

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<sup>3</sup> We note that Lacy discloses (column 9, lines 20-28), the digestible oil may be capric and/or caprylic triglyceride oils" including: "Miglyol 810, Miglyol 812, Neobee M5, Neobee 0, Captex 300, Captex 355 and Captex 8000." The examiner relies on Chavkin and Kikuchi to teach that capric triglyceride and MCTs, respectively, are structured lipids.

through column 5, line 26)] are capable of serving as the digestible oil component in this invention, or serving as the source of lipolytic products."

Therefore in a modification of Lacy's preferred carrier system a separate digestible oil component may be omitted. Accordingly, such a composition would include (1) a hydrophobic drug, (2) a hydrophilic surfactant, and (3) a lipophilic surfactant. Assuming, arguendo, Lacy's hydrophobic drug and lipophilic

surfactant are within the scope of appellants' claimed invention; Lacy's composition includes an additional component, a hydrophilic surfactant, which is specifically excluded from appellants' claimed invention. Accordingly, this embodiment of Lacy's disclosure does not support the examiner's position.

Lacy also carves out an exception to the use of lipophilic surfactants, we note that Lacy discloses (column 8, lines 14-18), this applies to "one class of hydrophilic surfactants, namely the transesterification products of polyoxyethylene glycol with glycerol esters of capric and caprylic acids ... [which do] not substantially inhibit the *in vivo* lipolysis of digestible oils." According to Lacy (column 8, lines 19-23), "with this class of hydrophilic surfactants there is no necessity to include any lipophilic surfactant component at all...."

Accordingly, Lacy discloses (column 8, lines 24-30):

[I]n a further aspect, the present invention provides a carrier system for a hydrophobic drug which comprises:

- (a) a digestible oil,
- (b) a transesterification product of polyoxy-ethylene glycol with glycerol esters of capric and/or caprylic acids as hydrophilic surfactant, and

(c) optionally a lipophilic surfactant.

Lacy discloses Labrasol (glyceryl caprylate/caprate and PEG-8 caprylate/caprate) and Softigen 767 (PEG-6 caprylic/capric glycerides) as examples of this type of hydrophilic surfactant. See Lacy, column 8, lines 31-37. Since this composition includes (1) a hydrophobic drug, (2) a digestible oil, and (3) a hydrophilic surfactant, this embodiment of Lacy's disclosure does not support the examiner's position either.

Therefore, while it may be true that Lacy suggests, under certain circumstances, that a digestible oil or a lipophilic surfactant is not necessary, and may be removed from Lacy's composition, for the foregoing reasons we find nothing in Lacy to suggest that even if these components were removed they would lead to appellants' claimed invention. Thus, as the examiner suggests (Answer, bridging sentence, pages 3-4), while it may have been obvious to one of ordinary skill in the art at the time the invention was made not to include a surfactant if it is deemed to be not necessary, for the foregoing reasons, there is no evidence on this record to suggest that a surfactant is indeed unnecessary.<sup>4</sup>

In this regard, we remind the examiner that "[t]he Patent Office has the initial

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<sup>4</sup> In this regard, we recognize the examiner's statement (Answer, page 5) that appellants' "specification clearly indicates that surfactants can be added (see example 1 in instant specification); in fact, it would appear from the comparison between figure 1 and figure 2, the plasma concentrations of fenofibrate are higher in the presence of surfactant than without it." In this regard, we remind the examiner "the name of the game is the claim." In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). On this record, the claims are limited to a composition (claims 1, 3-5, 12 and 14), or the use of a composition (claims 15 and 16) that consists of (1) a fibrate dissolved in (2) at least one structured lipid. Accordingly, notwithstanding the scope of appellants' disclosure, there is no surfactant in the claimed compositions or in the claimed methods of using these compositions.

duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). For the foregoing reasons, it is our opinion that the examiner has fallen "victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

Babayan, Bistrian and Hyltander whether applied alone or in combination fail to make up for the deficiency in Lacy. According to the examiner (Answer, page 4), "Babayan teaches that structured lipids do not elevate cholesterol levels when administered.... Bistraian [sic] teaches that structured lipids assist in fighting atherosclerotic problems.... Hyltander discusses the advantages of the structured lipids and emulsions containing these in clinical practice." Based on this evidence the examiner finds (id.),

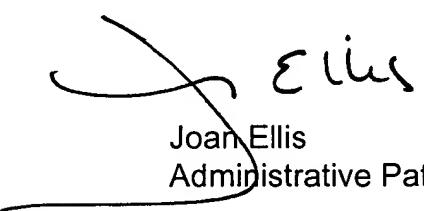
Assuming that Lacy's triglycerides are not structured lipids, it is deemed obvious to one of ordinary skill in the art to use the structured triglycerides instead of the triglycerides taught by Lacy, especially when the drug used is for regulating cholesterol or lipid metabolism, since structured triglycerides have advantages relating to cholesterol and atherosclerosis and other clinical advantages as taught by Babayan, Bistraian [sic] and Hyltander respectively.

However, for the foregoing reasons, we agree with appellants (Brief, bridging sentence, pages 8-9), "[e]ven if there were some proper motivation to substitute the structured lipids of the secondary references for the digestible oils of Lacy,

one would not obtain 'a composition consisting of a fibrate dissolved in at least one structured lipid' as required by the claims."

Accordingly, we reverse the rejection of claims 1, 3-5, 12, and 14-16 under 35 U.S.C. § 103 as being unpatentable over Lacy in view of Babayan, Bistraian and Hyltander.

REVERSED

  
Joan Ellis  
Administrative Patent Judge

  
Toni R. Scheiner  
Administrative Patent Judge

  
Donald E. Adams  
Administrative Patent Judge

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